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A feasibility and safety trial investigating a device for swift and standardized laparotomy closure

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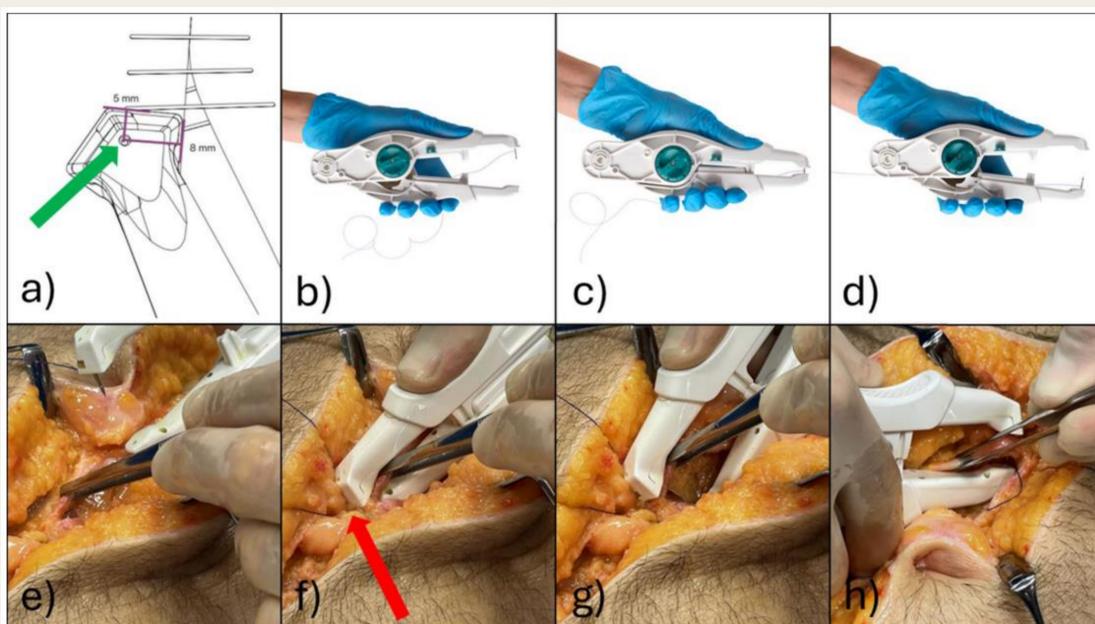
Conclusion

SutureTOOL is a promising device for clinical use. It ensures a fast and consistent small-bites laparotomy closure with a suture-length to wound-length (SL/WL) ratio ≥ 4 . The next steps involve a multi-center trial to evaluate the potential impact of SutureTOOL on short- and long-term complications related to the abdominal wall closure.

Method

- This was a prospective, one-armed, clinical trial evaluating laparotomy closure with a device for standardized laparotomy closure, SutureTOOL.
- Thirty-eight patients with colorectal disease, selected for laparotomy, were recruited.
- Five surgeons participated in the study.
- The primary endpoint was adherence to SL/WL ≥ 4 .
- Secondary endpoints included suturing time, bite-size, glove puncture rate, SSI, burst abdomen and adverse events.
- Learning curve was assessed by analyzing consecutive closure times.
- Follow-up included physical examination during hospital stay, postoperative visits and a chart review six weeks postoperatively.

The investigational device



The figure shows handling of the investigational device a) the front of the device's upper arm from above. The device has a guide at the front of the upper arm that facilitates small-bites placement. The guide is positioned adjacent to the previous stitch and with the lateral side towards the incision. Distance from the needle hole (green arrow) to the front of the guide is 5 mm and distance from the needle hole to the side of the guide is 8 mm. b) The device with a double-pointed needle attached in the upper arm. c) When the device is compressed the needle is transferred to the lower arm. d) Needle attached in the lower arm e) The forceps grab the contralateral edge of the midline aponeurosis. f) The guide (red arrow) is directed to the previous stitch. g) The lower arm of the device is released and the suture thread is pulled through the aponeurosis. h) The device is moved to the ipsilateral side of the incision to complete the stitch.

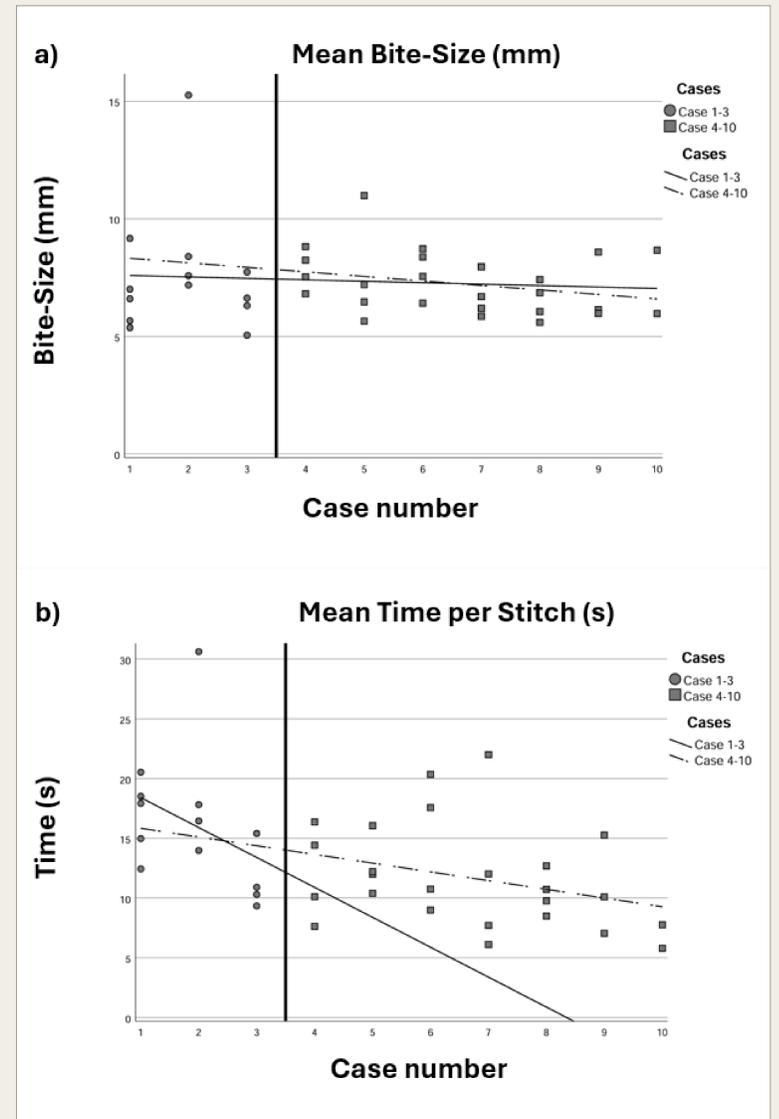


Figure shows all data points for a) bite-size (n=38) and b) time per stitch (n=38), for consecutive laparotomy closures (surgeons performed 1, 8, 9, 10 and 10 individual cases). Lines follow mean values. Straight lines follow cases 1-3 and dashed lines follow cases 4-10. mm, millimeter. s, seconds.

Results

- All patients received a SL/WL ratio ≥ 4 .
- Mean closure time was 7.4 min.
- The shortest closure time was 2.2 min.
- Mean bite-size was 7 mm.
- Learning curve levelled after three laparotomy closures.
- There were no glove punctures.
- One case of SSI was reported, and no burst abdomen was detected.
- No device related adverse events was detected.

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